REMARKS

The Office Action of January 22, 2009, and the applied prior art have been carefully reviewed. The claims in the application are now only claim 7 and 25, claim 7 having been amended to specify the object of the claimed method as "a type II diabetic patient", and claim 25 having been amended to correct typographical errors and to specify that the type of cell destruction is "ß-cell destruction". As the claims define patentable subject matter, applicants respectfully request favorable reconsideration and allowance.

As regards the claims objections of paragraph 3 of the Office Action, claim 16 is no longer pending, and so that objection need not be addressed at the present time. As regards claim 25, the typographical error has been corrected.

As regards the rejection under the second paragraph of §112, only claim 25 is presently pending among the claims rejected, so applicants need not address this rejection at the present time with respect to the claims other than claim 25.

With respect to the rejection of claim 25, such claim has been amended to specify that the type of cells are ß-cells.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1, 4, 21, 23 and 24 have been rejected under the first paragraph of §112. While applicants do not necessarily agree with this rejection, they need not address it at the present time in view of the cancellation of such claims without prejudice to applicants' rights to pursue such claims or similar claims at a later date, e.g. in a continuing application, without any penalty whatsoever, applicants in such a case relying on §§120 and 119.

Claims 7, 16, 22 and 25 have also been rejected under the first paragraph of §112, as purportedly lacking enablement except for the treatment of type II diabetes. This rejection is respectfully traversed for the record.

As claims 16 and 22 are no longer pending, applicants need not address the rejection with respect to these claims at the present time.

As regards claims 7 and 25, the rejection indicates that enablement is present with respect to the treatment of type II diabetes. Claims 7 and 25 have been so amended. Accordingly, the rejection should be withdrawn, and applicants respectfully request such withdrawal.

Claims 1, 4, 10, 16, 23 and 24 have been rejected under §102 as anticipated by newly cited Hussain U.S. patent application publication 2004/0136969 (Hussain '969). This rejection is respectfully traversed for the record.

The so rejected claims are no longer pending, so applicants need not address this rejection at the present time. However, applicants respectfully reserve the right to pursue these and/or similar claims in a continuing application without any penalty whatsoever, if applicants choose to do so, relying on §§120 and 119.

Claims 7 and 25 have been rejection as obvious under §103 from Krakowski in view of Hussain '969. This rejection is respectfully traversed.

Krakowski, previously applied under §102 against claims 1, 4, 7 and 16, was briefly discussed at page 14 of the preceding reply, where it was pointed out that Krakowski **at most** only discloses a therapeutic effect of GM-CSF for the treatment of diabetes, subject matter which applicants are not claiming; but actually, Krakowski discloses even less, namely that GM-CSF might "recruit, expand and activate antigen-presenting cells (APCs)". In more detail, Krakowski discloses that transgenic mice expressing GM-CSF within ß-cells of the pancreas are able to resist (delay and reduce) to some extent

the development of diabetes after being treated with streptozotocin (STZ).

Also, Krakowski is absolutely silent about the administration of GM-CSF, and of course is therefore also silent as to any effect which might be achieved by the administration of GM-CSF.

Hussain '969 discloses treating diabetic conditions as disclosed in Hussain by administering both bone marrow cells and GM-CSF to the mammal in question.

What can be logically learned from considering Krakowski and Hussain '969 together? Certainly, that GM-CSF by itself is not sufficient, i.e. at least either bone marrow cells per Hussain '969 are needed, or STZ is needed as required by Krakowski. But the present invention differs significantly and importantly because (1) applicants administer G-CSF rather than GM-CSF, and (2) applicants administer G-CSF by itself and not with either bone marrow cells or STZ.

One point therefore is that the prior art provides no reasonable expectation of success by the administration of even GM-CSF alone, let alone G-CSF. Another point is that the prior art provides **no reason** to administer G-CSF as claimed, and certainly no reason to administer G-CSF by itself.

As regards the differences between G-CSF and GM-CSF, the examiner maintains that Hussain '969 contemplates their use interchangeably and that this provides evidence of similar effects. But Hussain '969 provides no evidence whatsoever of any such equivalency, and those skilled in the art would never accept them as equivalent without at least some evidence of their equivalency, e.g. experimental data. Thus, example 5 of Hussain '969 demonstrates the use of GM-CSF, but applicants do not see any demonstration of the alleged equivalency.

Moreover, even if there were equivalency demonstrated in the prior art, this would not lead the person of ordinary skill in the art to any modification of Krakowski in view of Hussain '969 so as to reach the claimed subject matter. As noted above, there is an essential difference between the present invention and Hussain '969 in that administration of bone marrow cells in Hussain '969 is essential, whereas it is unnecessary to administer bone marrow cells in the present invention.

Applicants believe and respectfully submit that even if Krakowski and Hussain '969 were somehow obviously combined, the present invention, namely the administration of G-CSF without bone marrow cells, would not be achieved and would not have been obvious to the person of ordinary skill in the art,

so that the advantageous effects provided by the present invention cannot be reasonably expected from the prior art.

In this regard, the statement in the rejection at page 11 referring to paragraphs of the present application commencing with paragraph [0042] is incorrect because the portions of the specification commencing with paragraph [0042] are in relation to a different embodiment of the present application, which is no longer claimed and which corresponds to original claim 10.

Applicants believe and respectfully submit that the person of ordinary skill in the art, considering Krakowski and Hussain '969 together, would not have come up with the claimed method. It is applicants' specification, not available to the person skilled in the art at the time the present invention was made, which provides the incentive and reason to (1) shift from GM-CSF to G-CSF, and (2) to expect that the administration of G-CSF by itself would provide any useful result. Withdrawal of the rejection is in order and is respectfully requested.

Claims 1, 4, 7, 16 and 23-25 have been rejected as obvious from Lukic in view of Dalhoff and further in view of newly cited and applied Maedler et al, J. Clinical

Investigation, 2002 (Maedler). This rejection is respectfully traversed.

As claims 1, 4, 16, 23 and 24 are no longer pending, applicants need not address this rejection as regards those claims at the present time.

As regards 7 and 25, applicants repeat by reference the remarks of the preceding reply commencing at the bottom of page 14, with respect to the proposed combination of Lukic in view of Dalhoff.

Applicants do not see that Maedler makes up for the deficiencies of the proposed combination of Lukic in view of Dalhoff as set forth in the preceding reply. Applicants believe and respectfully maintain that **no reason** exists for the proposed combination. Applicants further believe and respectfully submit that considering the three references together would still give no reasonable expectation of applicant's results.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 10, 21 and 22 have been further rejected under §103 based on combinations of cited references. However, applicants need not address these rejections at the present time in view of the deletion of these claims without

prejudice, applicants respectfully reserving the right to return to these and/or similar claims at a later date, without any penalty whatsoever, for example in a continuation application.

As regards the prior art documents made of record both earlier and more recently, and not relied upon by the PTO, applicants understand that such documents are considered to be insufficiently material by the PTO to warrant application against any of applicants' claims.

All issues in the Office Action of January 22, 2009, having been addressed above in a manner which applicants believe should lead to patentability, applicants respectfully request favorable reconsideration and allowance.

Respectfully submitted,

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